IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MARINA QUIROZ, ***Plaintiff*****,**	)	**CASE No.: _____**
v.	)	
ASTORA WOMEN'S HEALTH SYSTEM, LLC, and AMERICAN MEDICAL SYSTEMS, INC.,	)	**COMPLAINT FOR DAMAGES JURY TRIAL REQUESTED**
Defendant**.**	)	

COMPLAINT FOR DAMAGES AND JURY DEMAND

Plaintiff MARINA QUIROZ ("Plaintiff") files this Complaint and for causes of action against Defendants AMERICAN MEDICAL SYSTEMS, INC., AMERICAN MEDICAL SYSTEMS HOLDING, INC., ASTORA WOMEN'S HEALTH, LLC, ENDO PHARMACEUTICALS, INC., ENDO PHARMACEUTICALS HOLDINGS, INC., AND ENDO HEALTH SOLUCTIONS, INC. (collectively, "AMS Defendants" or "AMS"), alleges as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than one or more of the Defendants.

2. At all times material hereto, AMS Defendants were engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting, and/or selling in interstate commerce throughout the United States, including Texas, either directly or indirectly, medical devices intended to treat stress urinary incontinence and/or pelvic organ

prolapse, including the Monarc subfascial hammock system (the "Monarc") that was used to implant the Monarc into Plaintiff in Texas.

3. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district. Specifically, Plaintiff was implanted with the product at issue in this district and was injured in this district.

4. AMS Defendants are subject to *in personam* jurisdiction in the U.S. District Court for the Southern District of Texas because AMS Defendants placed defective products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Plaintiff, a Texas resident, in the State of Texas. Each Defendant has sufficient minimum contacts in Texas or otherwise intentionally avails itself of the Texas market through, without limitation, its advertisement, promotion, marketing, sales, and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the Texas courts consistent with traditional notions of fair play and substantial justice.

PARTIES

5. Plaintiff MARINA QUIROZ is a citizen and resident of Texas who was implanted with AMS Defendants' defective medical device in Houston, Texas.

6. Defendant ASTORA WOMEN'S HEALTH, LLC ("Astora'), formerly known as American Medical Systems, Inc., survivor of merger with or acquiring corporation of AMS, Inc. and/or AMS Holdings, Inc, may be served pursuant to 10 Del. C. § 3111 by serving registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. ASTORA WOMEN'S HEALTH, LLC is a Delaware limited liability company, and its sole member is Endo Pharmaceuticals, Inc., a Delaware corporation with its principal place of

business in Pennsylvania.

7. Defendant AMERICAN MEDICAL SYSTEMS, INC. ("AMS"), now known as Astora Women's Health, LLC was a Delaware corporation with its principal place of business in Minnesota and may be served pursuant to 10 Del. C. § 3111 by serving registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

FACTUAL BACKGROUND

A. History and Relationship of AMS Defendants

8. American Medical Systems, Inc. ("AMS"), a corporation formed pursuant to the laws of the State of Delaware, obtained clearance from the FDA and designed, developed, manufactured, marketed, distributed, and sold products to treat pelvic organ prolapsed and/or stress urinary incontinence, including the AMS Monarc Sling that is the subject of this lawsuit. On information and belief, American Medical Systems, Inc. changed its name to, merged with, or was otherwise subsumed by Astora Women's Health, LLC. These entities are sometimes collectively referred to herein as the "AMS Defendants."

9. The subject synthetic mesh system as designed, manufactured, marketed, distributed, sold and/or supplied by AMS and/or Astora Women's Health was defective as marketed due to defective design and inadequate warnings in the presence of AMS and/or Astora Women's Health's knowledge of lack of pelvic health safety and lack of efficacy.

B. The Pelvic Mesh Product

10. The AMS Defendants and promoted their medical devices as devices intended to treat stress urinary incontinence ("SUI") and/or pelvic organ prolapse ("POP").

11. The AMS Defendants designed, manufactured, packaged, labeled, marketed, sold, and distributed the AMS Monarc which was implanted in Plaintiff.

12. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP and SUI. Manufacturers, including the AMS Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and/or SUI. The AMS Defendants sold pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools.

13. The AMS Defendants sought and obtained FDA clearance (not approval) to market the AMS Monarc Sling (hereinafter the "Monarc") under Section 510(k) of the Medical Device Amendment to the Food, Drug, and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by the AMS Defendants with regard to its polypropylene pelvic mesh products, including the Monarc and its predicate devices.

14. The AMS Defendants' pelvic mesh products, including the AMS Monarc and its predicate devices, contain monofilament polypropylene mesh. The AMS Defendants represent that these pelvic mesh products were designed and intended to be permanently implanted into the human body. Despite claims that polypropylene is inert, the scientific evidence shows that this material, as implanted in Plaintiff, is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with polypropylene pelvic mesh products, including the Monarc at issue herein. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions

to the mesh. When this mesh is inserted according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

15. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of SUI. These products include products manufactured, marketed, and distributed by Defendant. These products were and are approved by the FDA under the abbreviated 510(k) approval process. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to these pelvic mesh products, including the Monarc device at issue in this case.

16. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff and others is biologically incompatible with human tissue, and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products.

17. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers should have been aware of this literature.

a. Shrinkage and bacteria lead to an evolving process and increased erosion (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).

b. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).

c. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages (Osterberg B. ActaChirScand1979; 145:431, Merritt K. J BiomatAppl 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).

d. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

e. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

f. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached from the polypropylene and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol 2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984; 10:163).

g. Prolene (polypropylene) was shown to be not inert in 1986 and again in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions (Coda A. Hernia 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).

h. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).

i. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., Tensile properties of commonly used prolapse meshes. Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.

j. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol, 2004. 171(5): p. 1970-3.

k. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. Curr Opin Obstet Gynecol. 2002; 14:527–595. 22. Govier FE, Kobashi KC,

Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. J Urol. 2005;65:1099–1103.

18. When Pelvic Mesh Products, like the Monarc Sling System, are inserted in the female body according to manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

19. The Monarc procedure is performed by inserting the two helical needles blindly into the incisions in the inner thigh through the obturator membrane**,** around ischiopubic rami, and through a vaginal incision to place a polypropylene mesh under the urethra (otherwise known as an "out-to-in placement").

20. Synthetic materials like polypropylene, including that used by AMS in its pelvic mesh products like the Monarc and its predicate devices, are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh.

21. The polypropylene mesh used by AMS Defendants for their pelvic mesh products, including the Monarc and its predicate devices, also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on their anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these

transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping, and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

22. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare."

23. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA." Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening, and vaginal pain.

24. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur…[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

25. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS

takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms."

26. The AMS Defendants did not, and have not, adequately studied the extent of the risks associated with their pelvic mesh products, including the Monarc.

27. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating: "There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable."

28. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

29. Plaintiff's injuries, as will be more fully established in discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

30. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

31. Contemporaneously with the Safety Communication, the FDA released a

publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

32. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk."

33. The FDA White Paper further stated that, "these products are associated with serious adverse events…compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

34. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

35. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.

36. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing

their products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[1]

37. AMS knew known about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the FDA Advisory that addressed the sales of transvaginal mesh implants for pelvic organ prolapse.

38. AMS has further known the following:

a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Product was and is causing numerous patients severe injuries and complications.

39. AMS suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, AMD actively and intentionally misled and continues to mislead the public into believing that the

[1] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited 06/15/2021).

Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

40. AMS failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

41. AMS failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

42. Feasible, reasonable, and suitable alternative designs as well as reasonable suitable alternative procedures and instruments for repair of stress urinary incontinence have existed at all times relevant to this matter, including, but not limited to the following: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a sling made with DynaMesh or other Polyvinylidene fluoride (PVDF) alternative; a retropubic sling; a retropubic mini-sling, such as the TFS device from TFS Surgical; or a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as DynaMesh or other Polyvinylidene fluoride (PVDF) alternative.

43. The Pelvic Mesh Product was at all times utilized and implanted in a manner foreseeable to AMS, as it generated the directions for use, created the procedures for implanting the device, and trained the implanting physicians.

44. AMS provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of these products.

45. The Pelvic Mesh Product implanted into Plaintiff Marina Quiroz was in the same or substantially similar condition as it was when it left the possession of Defendant, as well as

being in the condition directed by and expected by Defendant.

46. Plaintiff Marina Quiroz and her physician foreseeably used and implanted the Pelvic Mesh Product and did not misuse or alter these products in an unforeseeable manner.

47. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Product include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, pelvic floor damage, myofascial pain, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

48. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

49. AMS knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

50. At all relevant times herein, AMS continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term

efficacy.

51. At all relevant times herein, AMS failed to provide sufficient warnings and instructions that would have put the Plaintiff, her treating physicians, and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products, including the Monarc product at issue in this case.

52. The Pelvic Mesh Products, including the Monarc product at issue in this case, were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

53. The Monarc is designed to be inserted into and through the obturator internus muscle, producing a foreseeable risk of acute and chronic myofascial pain as well as a foreseeable risk of (1) obturator neuralgia, by virtue of its passage through the obturator internus muscle, and (2) pudendal neuralgia, by virtue of its passage through the obturator internus muscle which runs alongside the pudendal nerve as the pudendal nerve passes through Alcock's Canal. Defendant failed to study or account for anatomic variations of the pudendal nerve when designing the device.

54. The Monarc was designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, bladder function, and chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also cause fibrosis of muscles, adhesions between tissues, and inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic pelvic pain, neuralgia, among other mesh-related issues.

55. As the AMS Defendants are well aware, the risks associated with POP repair using a polypropylene product are the same as those for SUI repair using a polypropylene product, like the Monarc. However, the data regarding the magnitude and frequency of these known risks are

not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued in January of 2012 to manufacturers of pelvic mesh products used to treat SUI.

56. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur…[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

C. Defective Design

57. Defendant knew or should have known that its Pelvic Mesh Products, including the Monarc pelvic mesh product at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing the Monarc, Defendant was aware that the Monarc was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

58. The Monarc designed to be permanently implanted into a woman's body yet the products change after implantation; the mesh contracts over time which inter alia, can pull or compress nerves, muscles, and other soft tissues important for sexual function, mobility, bowel function, and bladder function. These product changes occur while the product is implanted.

59. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic

inflammatory response in a large subset of the population implanted with AMS Defendants' Pelvic Mesh Products, including the Monarc, the product at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

60. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

61. AMS Defendants' Pelvic Mesh Products, including Monarc, were and are unreasonably susceptible to degradation and fragmentation inside the body, shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory response, chronic wound healing, chronic infections in and around the mesh fibers, and nerve entrapment in the collagen scar formation. Defendant knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks to the extent they were known or knowable.

62. The AMS Defendants did not, and have not, adequately studied the extent of the risks associated with AMS pelvic mesh products, including the Monarc at issue. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these

risks.

63. The AMS Defendants knew or should have known about AMS pelvic mesh products', including the Monarc's, risks and complications identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the FDA Advisory.

64. The AMS Defendants knew or should have known that AMS Pelvic Mesh Products, including the Monarc, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

65. The scientific evidence shows that the material from which AMS pelvic mesh products, including the Monarc, is made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the AMS Defendants' product, including Plaintiff.

66. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

67. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." AMS pelvic mesh products, including the Monarc at issue, were unreasonably susceptible to degradation and fragmentation inside the body.

68. AMS pelvic mesh products, including the Monarc at issue, were unreasonably susceptible to shrinkage and contraction inside the body. Before the device at issue left control of the AMS Defendants and/or prior to the sale and/or implantation of the product at issue, the AMS

Defendants knew or should have known of this serious risk related to shrinkage and contraction of their permanent synthetic vaginal mesh products and warned physicians and patients.

69. AMS pelvic mesh products, including the Monarc at issue, were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body. Before the device at issue left control of the AMS Defendants and/or prior to the sale and/or implantation of the products at issue, the AMS Defendants knew or should have known that their products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

70. The Monarc has been, and continues to be, marketed to the medical community and to patients as safe, effective, and reliable medical devices, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective than other available feasible alternative treatments of stress urinary incontinence and pelvic organ prolapse, such as use of native tissue and other competing products.

71. The AMS Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of AMS pelvic mesh products, including the Monarc. Through their inadequate warnings, the AMS Defendants promoted the Monarc as a safe medical device when they knew or should have known that the Monarc was not safe for its intended purposes and that the Monarc would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Monarc were made known to physicians, the full magnitude, severity, and frequency of these problems were not disclosed and were hidden from physicians, including Plaintiff's physicians.

72. Contrary to the AMS Defendants' representations and marketing to the medical community and to the patients themselves, the Monarc has a high rate of failure, injury, and

complications, fails to perform as intended, require frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making these products defective under the law.

73. Defendant failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products, including the Monarc, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

74. Feasible, suitable, and safer alternative designs to AMS Defendants' Pelvic Mesh Products, have existed at all times relevant and in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the products' utility. These safer alternative designs were economically and technologically feasible at the time the Pelvic Mesh products left the control of Defendant by the application of existing or reasonably achievable scientific knowledge. Safer alternatives designs for the Monarc included but were not limited to: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic mini-sling, such as the TFS device from TFS Surgical; or a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as DynaMesh or other Polyvinylidene fluoride (PVDF) alternative.

75. The specific nature of the Monarc's defects includes, but is not limited to, the following:

a. The use of polypropylene and the adverse tissue reactions, host defense response, and immune reactions that result from such material, causing adverse reactions and permanent injuries including but not limited to painful recurrent erosions and associated intractable pain;

b. The design to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss

and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

c. The design to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

d. Biomechanical issues with the design, including, but not limited to, the propensity to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in serious and permanent injury;

e. The use and design of arms and/or anchors, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

f. The procedure for placement requires blindly placing the arms of the device that can injure the ilioinguinal nerve and pudendal nerve;

g. The propensity for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

h. The inelasticity, causing the products to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, or walking);

i. The propensity for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

j. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

D. Failure to Warn/Inadequate Warnings & Instructions

76. The Monarc is also defective due to the AMS Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The propensities of the device to contract, retract, and/or shrink inside the body;

b. The propensities of the device for degradation, fragmentation, and/or creep;

c. The inelasticity of the device that prevents proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the device;

f. The risk of chronic infections resulting from the device;

g. The risk of permanent vaginal or pelvic scarring as a result of the device;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual intercourse;

j. The risk of recurrent, intractable pelvic pain and other pain resulting from the device;

k. The need for corrective or revision surgery to adjust or remove the device;

l. The severity of complications that could arise as a result of implantation of the device;

m. The hazards associated with the device, including injury to the obturator nerve, pudendal nerve, or other permanent nerve damage;

n. The defects of the device described herein;

o. Treatment of stress urinary incontinence with the device is no more effective than feasible available alternatives;

p. Treatment of stress urinary incontinence with the device exposes patients to greater risk than feasible available alternatives;

q. Treatment of stress urinary incontinence with the device makes future surgical repair more difficult than the feasible available alternatives;

r. Use of the device puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

s. Removal of the device due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. Complete removal of the device may not be possible and may not result in complete resolution of the complications, including pain.

u. The nature, magnitude, and frequency of the complications that could arise as a result of implantation of the Pelvic Mesh Products.

77. The AMS Defendants under-reported and continue to under-report information about the propensity of their polypropylene products, including the Monarc and its predicate devices, to fail and to cause injuries, and complications, and have made unfounded representations regarding the efficacy and safety of the Monarc through various means and media.

78. AMS failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Monarc.

79. The AMS Defendants failed to design and establish a safe, effective procedure for removal of the Monarc, or to determine if a safe and effective procedure for removal of products exists.

80. Feasible and suitable alternatives to the Monarc have existed at all times relevant and do not present the same frequency or severity of risks as the Monarc.

81. The Monarc implanted into Plaintiff was at all times utilized and implanted in a manner intended and foreseeable to the AMS Defendants, as the AMS Defendants generated the instructions for use, created the procedures for implanting the device, and trained or instructed the implanting physician(s) with regard to use of the device.

82. The AMS Defendants knowingly provided incomplete and insufficient training and information to physicians, including Plaintiff's implanting physician(s), regarding the use of their pelvic mesh products, including the Monarc, and the aftercare of patients implanted with those products.

83. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Monarc include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain

during sexual intercourse), obturator neuralgia, pudendal neuralgia, blood loss, neuropathic pain, and other acute and chronic nerve damage and pain, nerve damage, pelvic floor damage, and chronic pelvic pain and extrapelvic pain.

84. In many cases, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

85. The medical and scientific literature studying the effects of mesh products like the Monarc implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to polypropylene mesh products.

86. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

87. At all relevant times herein, the AMS Defendants continued to promote the pelvic mesh products, including the Monarc, as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

88. The Monarc was at all times utilized and implanted in a manner intended and/or foreseeable to AMS, as AMS generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

89. AMS knowingly provided incomplete and insufficient training and information to physicians regarding the use of its Pelvic Mesh Products, including the Monarc device at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

90. In doing so, the AMS Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Monarc and its predicate devices, including the magnitude, severity, and frequency of these risks.

91. At all relevant times herein, the AMS Defendants failed to provide sufficient warnings and instructions that would have put physicians, Plaintiff, and the general public on notice of the dangers and adverse effects caused by implantation of the Monarc.

92. The Monarc, as designed, manufactured, distributed, sold and/or supplied by AMS, was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of AMS Defendants' knowledge of lack of safety

93. The risk of serious injuries was known or should have been known to AMS, but in spite of these risks, AMS Defendants continued to market the Monarc for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

94. The Monarc was designed to be placed on or about the pelvic floor adjacent to the vagina, the urethra, the bladder, and the rectum. This intended placement causes or substantially contributes to causing pelvic floor myalgia, painful bladder filling, chronic pelvic pain, impaired mobility, impaired sexual function, dyspareunia, impaired bladder function, recurrent infections, recurrent incontinence, impaired bowel function, and impaired mobility related to chronic inflammatory response, scar plate formation, adhesions, and erosions and migration of the mesh, including the Monarc.

95. The Monarc is designed to require blindly placing the arms of the sling and does not account for anatomic variations of the ilioinguinal nerve and the pudendal nerve branch to the clitoris.

96. The AMS Defendants did not design the Monarc to account for the anatomic variations known for the pudendal, ilioinguinal, and obturator nerves or adequately warn of this design issue.

E. Resulting Injury From AMS Defendants' Pelvic Mesh Product

97. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with AMS Defendants' Pelvic Mesh Products include, but are not limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, affected women, including Plaintiff, will need to be continuously monitored because of being implanted with Defendant's Pelvic Mesh Products.

98. In many of these cases, including that of the Plaintiff, women have had or will have to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

99. The medical and scientific literature studying the effects of pelvic mesh products, like that of the Monarc device implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the pelvic mesh

products.

F. Plaintiff's Monarc Implantation

100. On information and belief, Dr. Geoffrey Schnider, M.D. recommended the Monarc to Plaintiff Marina Quiroz as appropriate and safe for the treatment of her stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Monarc.

101. On May 27, 2015, Plaintiff Marina Quiroz underwent surgery to address her stress urinary incontinence at Fannin Surgicare in Houston, Texas, with Dr. Geoffrey Schnider, M.D. During this surgery, Ms. Quiroz was implanted with an AMS Monarc sling.[2]

102. Plaintiff's treating physician implanted the Monarc properly and appropriately. The Monarc that was implanted in Plaintiff was without substantial alteration and in the same or substantially similar condition as when it left the AMS Defendants' possession, and in the condition directed by and expected by the AMS Defendants.

103. On September 4, 2019, Plaintiff underwent a procedure for laparoscopy, lysis of adhesions, and vaginal excision of the Monarc sling.

104. As a direct and proximate cause of having the Monarc device implanted in her, Plaintiff Marina Quiroz has experienced significant mental and physical pain and suffering, including dyspareunia that makes vaginal penetration impossible, mobility problems, anal-rectal pain, clitoral numbness, neuromuscular pain, disabling pelvic pain, abdominal pain, hip pain, groin pain, perineal pain, recurrence of incontinence, perforation and vaginal scarring, surgical sling revision, and has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. In addition or in the

[2] Monarc Subfascial Hammock. Lot # 929482058, Ref # 72403830.

alternative, Plaintiff has suffered an aggravation, exacerbation, and/or acceleration of her pre-existing injuries or conditions.

DISCOVERY RULE/FRAUDULENT CONCEALMENT

106. Plaintiff realleges and incorporates by reference paragraphs 1-105 of this Complaint as if each were set forth fully and completely herein.

107. Plaintiff could not have reasonably discovered the occasion, manner, and/or means by which AMS Defendants' breach of duty occurred until within two years of the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence (including consultation with medical professionals) could not, discover the existence of her legal cause of action or the injuries caused by the AMS Defendants' breach of duty and/or defective products until within two years of the filing of this complaint.

108. Neither Plaintiff nor her healthcare providers were warned that the Monarc was unreasonably dangerous or of the risks of the device, outlined herein, even when used exactly as intended by the AMS Defendants. To the contrary, the AMS Defendants promoted and sold the type of transvaginal mesh devices implanted in Plaintiff and thousands of women like Plaintiff to healthcare providers as a safe alternative to other procedures that did not incorporate the AMS Defendants' products.

109. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, .and the tortious nature of the wrongdoing that caused the injury.

110. Pleading further, AMS Defendants continue to deny that their products are

defective or cause injuries such as those suffered by Plaintiff, and AMS Defendants continued to manufacture and sell the products at issue and/or related or predicate products. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material facts known by the AMS Defendants when they had a duty to disclose and/or by the application of the discovery rule.

111. As a result of AMS Defendants' fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of AMS Defendants.

112. To the extent further pleading be necessary, Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations.

FIRST CAUSE OF ACTION
[Negligence]

113. Plaintiff realleges and incorporates by reference paragraphs 1-112 above as if each were set forth fully and completely herein.

114. At all times herein mentioned, AMS Defendants were engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging and advertising the Monarc device at issue in this case.

115. AMS Defendants owe to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in pursuit of the activities mentioned above, and AMS Defendants breached said duty of care.

116. At all times relevant hereto, AMS Defendants owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Monarc, and to adequately test and warn of the risk and dangers of the Monarc, both before and after sale.

117. Additionally, AMS Defendants owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Monarc manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Monarc to perform as intended or as an ordinary consumer would expect.

118. AMS Defendants further breached their duty of care in the testing of its Pelvic Mesh Products, including the Monarc device at issue in this case, by failing to conduct adequate testing to ensure that the Monarc was reasonably safe for implantation in the female pelvic area prior to releasing the Monarc into the market, failing to conduct post-launch testing following adverse findings in the scientific and medical literature, and by failing to conduct post-launch testing to investigate and evaluate reports in the FDA adverse event databases for their potential significance for AMS Defendants' Pelvic Mesh Products, including the Monarc device at issue in this case.

119. AMS Defendants breached the duty to take all reasonable steps necessary to manufacture and sell products that were not defective or unreasonably dangerous to consumers and users of the products, including Plaintiff herein. AMS Defendants were negligent in failing to

use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Monarc device at issue herein. AMS Defendants breached the aforementioned duties in that AMS Defendants negligently and carelessly designed, licensed, inspected or failed to inspect, tested or failed to test, inadequately warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, and advertised the Monarc in that said device caused, directly and proximately, the injuries of Plaintiff through failure of the Monarc to perform as intended or as an ordinary consumer would expect. AMS Defendants breached the aforementioned duty by, among other things:

a. Failing to design the Monarc so as to avoid an unreasonable risk of harm to women in whom the Monarc at issue herein was implanted, including Plaintiff;

b. Failing to manufacture the Monarc device at issue herein so as to avoid an unreasonable risk of harm to women in whom the Monarc were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Monarc device at issue herein so as to avoid an unreasonable risk of harm to women in whom the device was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Monarc device at issue herein so as to avoid an unreasonable risk of harm to women in whom the Monarc was implanted, including Plaintiff;

e. Failing to use reasonable care in the training and instruction to physicians

for the safe use of the Monarc;

f. Failing to use reasonable care in studying the Monarc to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Monarc.

120. AMS Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The use of polypropylene and/or collagen material in the Monarc and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Monarc to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Monarc, including, but not limited to, the propensity of the Monarc to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Monarc, which, when placed in women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Monarc for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. The inelasticity of the Monarc at issue herein, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Monarc at issue herein for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the Monarc, which are causally related to infection, as the polypropylene is a foreign material; and

k. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

121. AMS Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Monarc's propensities to contract, retract, and/or shrink inside the body;

b. The Monarc's propensities for degradation, fragmentation and/or creep;

c. The Monarc's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Monarc;

f. The risk of chronic infections resulting from the Monarc;

g. The risk of permanent vaginal or pelvic scarring as a result of the Monarc;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Monarc;

i. The need for corrective or revision surgery to adjust or remove the Monarc;

j. The severity of complications that could arise as a result of implantation of the Monarc including obturator neuralgia, pudendal neuralgia, and other permanent nerve damage;

k. The hazards associated with the Monarc;

l. The Monarc's defects described herein;

m. Treatment of stress urinary incontinence with the Monarc is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Monarc exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Monarc makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Monarc puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Monarc due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Monarc may not be possible and may not result in complete resolution of the complications, including pain.

122. As a proximate result of AMS Defendants' negligent design, marketing, and testing of their Pelvic Mesh Products, including the Monarc device at issue in this case, Plaintiff has been injured catastrophically, sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages. In addition or in the alternative, Plaintiff has suffered an aggravation, exacerbation, and/or acceleration of her pre-existing injuries or conditions.

123. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

124. WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

SECOND CAUSE OF ACTION
[Strict Liability: Design]

125. Plaintiff realleges and incorporates by reference paragraphs 1-124 as if each were set forth fully and completely herein.

126. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

127. AMS Defendants were and are engaged in the business of selling its pelvic mesh products, including the Monarc device at issue, in the State of Texas.

128. AMS Defendants are manufacturers and/or suppliers of Pelvic Mesh Products, specifically the Monarc pelvic mesh product, and are strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling and placing their Pelvic Mesh Products, specifically Monarc, into the stream of commerce.

129. The Monarc was designed, marketed, manufactured and distributed by the AMS Defendants and was defective and not reasonably safe due to their improper, inadequate, and defective design.

130. The Monarc device manufactured, designed, marketed, promoted, and sold by AMS Defendants was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold and in the condition directed by and expected by AMS Defendants. The Monarc was defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale and distribution, and at the time they left the possession of the AMS Defendants.

131. AMS Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Monarc and Plaintiff was an expected user or consumer of the mesh products.

132. AMS Defendants' Pelvic Mesh Products, including the Monarc device at issue in this case, were defectively and improperly designed, rendering the products deficient and unreasonably dangerous and hazardous to Plaintiff.

133. The Monarc device that was implanted in Plaintiff was conveyed in a condition not contemplated by reasonable persons among those considered expected users or consumers of the pelvic mesh products, like Plaintiff.

134. AMS Defendants' Pelvic Mesh Products, specifically the Monarc, manufactured

and/or supplied by AMS Defendants, were defective in design or formulation in that, when they left the hands of Defendant, and they were unreasonably dangerous, taking into consideration the utility of these products and the risks involved in their use.

135. The Monarc that was implanted in Plaintiff were, at the time conveyed, not in conformity with the generally recognized state of the art applicable to the safety of the products at the time the products were designed, manufactured, packaged, labeled and/or sold. There were also safer alternative designs for the devices.

136. The Monarc that was implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein with respect to its design. These design defects include, but are not limited to, the following:

a. The use of polypropylene in the Monarc and the foreseeable adverse tissue reactions, host defense response, and immune reactions that result from such material leading to ongoing degradation of the mesh, shrinkage, perpetual scarification as the mesh degrades all of which have potential to produce adverse reactions and permanent injuries including but not limited to painful recurrent erosions, direct muscle and soft tissue injury, nerve entrapment or irritation of adjacent nerves, and associated intractable neuropathic pain and myofascial pain;

b. The design of the Monarc to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical

infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

c. The design of the Monarc to be inserted into and through the groin/obturator internus muscles produces a foreseeable risk of acute and chronic myofascial pain;

d. The design of the Monarc to be inserted into and through the groin/obturator internus muscles produces a foreseeable risk of obturator and pudendal neuralgia that may present acutely or months to years after implantation;

f. The design of the Monarc to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

g. Biomechanical issues with the design of the Monarc, including, but not limited to, the propensity of the mesh in the Monarc to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in serious and permanent injury to the soft tissues and muscles of the pelvic floor without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

h. The use and design of arms and anchors in the Monarc device at issue herein, which, when placed in women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

i. The propensity of the Monarc for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

j. The inelasticity of the Monarc, causing the product to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, or walking) without providing any additional therapeutic benefit when compared to other surgical treatment options for SUI:

k. The propensity of the mesh in the Monarc to degrade or fragment over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

l. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

m. The propensity of the mesh in the Monarc to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

n. The hardening of the Monarc in the body;

o. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions that are unique to polypropylene without

providing any additional therapeutic benefit when compared to other non-polypropylene surgical treatment options for SUI;

p. The use of polypropylene material in the Monarc and the failure to provide adequate instructions for use ("IFU") and training.

137. As designed, AMS Defendants' Pelvic Mesh Products, including the Monarc at issue in this case, were and are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

138. AMS Defendants' Pelvic Mesh Products, including the Monarc at issue in this case, create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

139. AMS Defendants' Pelvic Mesh Products, including the Monarc at issue in this case, are not reasonably safe and so likely to be harmful to users that a reasonable person who had actual knowledge of their potential for producing injury would conclude that it should not have been marketed.

140. AMS Defendants' Pelvic Mesh Products, including the Monarc at issue in this case, are dangerous beyond that which would be contemplated by an ordinary person, doctor, or patient with the ordinary knowledge common to the community as to its characteristics.

141. AMS Defendants have intentionally and recklessly designed, marketed, labeled, sold, and distributed its Pelvic Mesh Products (including the Monarc at issue in this case) with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing its economic interests above the health and safety of Plaintiff.

142. At all relevant times, feasible, safer mesh-related alternative designs to the Monarc pelvic mesh product existed, such as the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic sling; a retropubic mini-sling, such as the TFS device from TFS Surgical; or a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF).

143. With respect to Plaintiff in particular, flaws with the Monarc's design, including but not limited to the use of polypropylene mesh in the Monarc, the weight and pore size of the polypropylene mesh used in the Monarc, and the transobturator design of the Monarc device[3], caused and created chronic inflammation and chronic foreign body reaction inside of Plaintiff, as well as entrapment, aggravation, irritation and/or compression of Plaintiff's obturator, pudendal, and/or ilioinguinal nerves, which in turn damaged and aggravated the surrounding soft tissues. As a direct and proximate result of these design flaws, Plaintiff has suffered and in all reasonable probability will continue to suffer from dyspareunia that makes penetration impossible, neuromuscular pain, nerve damage, pelvic pain, extrapelvic pain, hip pain, groin pain, vaginal pain, thigh pain, perineal pain, anal-rectal pain, clitoral numbness, paresthesia, depression, and impairment of bowel and bladder function, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, loss of enjoyment of life, and economic damages. In addition or in the alternative,

[3] As stated previously, the transobturator design of the Monarc requires it be inserted into and through the obturator internus muscle, producing a foreseeable risk of acute and chronic myofascial pain as well as a foreseeable risk of: (1) obturator neuralgia, by virtue of its passage through the obturator internus muscle, and (2) pudendal neuralgia, by virtue of its passage through the obturator internus muscle which runs alongside the pudendal nerve as the pudendal nerve passes through Alcock's Canal.

Plaintiff has suffered an aggravation, exacerbation, and/or acceleration of her pre-existing injuries or conditions.

144. As a direct and proximate result of the wrongful acts and omissions of AMS Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

145. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

146. WHEREFORE, Plaintiff demands judgment against AMS Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

THIRD CAUSE OF ACTION
[Strict Liability: Marketing/Failure to Warn]

147. Plaintiff realleges and incorporates by reference paragraphs 1-146 of this Complaint as if each were set forth fully and completely herein.

148. AMS Defendants supplied the Monarc that was implanted in Plaintiff.

149. AMS Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Product at issue herein.

150. The Monarc was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the products, making the products unreasonably dangerous.

151. AMS Defendants' Monarc is defective due to AMS Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects.

152. In their IFUs, as well as the marketing materials they prepared and disseminated to

patients and healthcare providers, AMS Defendants omitted critical information regarding the risks and potential complications of the Monarc at issue in this case. Specifically, AMS Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the following (subsequently referred to as the "Risks and Potential Complications"):

a. That the Monarc was not studied prior to launch for safety and efficacy;

b. That the Monarc has the propensity to contract, retract, and/or shrink inside the body;

c. That the Monarc has propensities for degradation, fragmentation, and/or creep;

d. That the Monarc's inelasticity prevents proper mating with the pelvic floor and vaginal region;

e. The magnitude of the risk of mesh erosion or extrusion;

f. The risk of chronic inflammation resulting from the Monarc;

g. The risk of chronic infections resulting from the Monarc;

h. The risk of developing chronic regional pain syndrome as a result of chronic inflammation/infection;

i. The risk of permanent vaginal or pelvic scarring as a result of the Monarc;

j. The risk of recurrent, intractable pelvic pain, extrapelvic pain, groin pain, thigh pain, nerve pain, and other pain resulting from the Monarc;

k. The risk of direct nerve injury to the obturator nerve;

l. The risk of secondary nerve irritation to the obturator nerve;

m. The risk of secondary nerve irritation to the pudendal nerve;

n. The magnitude of the risk of dyspareunia (painful sexual intercourse) in patients;

o. That the Monarc may result in dyspareunia that makes vaginal penetration impossible;

p. The frequency with which the need for corrective or revision surgery to adjust or remove the Monarc may occur in patients;

q. The magnitude of the risk of acute and long-term complications that could arise as a result of implantation of the Monarc in patients;

r. The hazards associated with the Monarc, including obturator, pudendal, and ilioinguinal neuralgia, permanent nerve damage, and pelvic floor and groin myalgia;

s. That treatment of SUI with the Pelvic Mesh Product exposes patients to greater risk than feasible available devices for SUI, including pelvic mesh products utilizing alternative polypropylene material or non-polypropylene surgical products, alternatives, and procedures;

t. That treatment with the Monarc makes future surgical repair more difficult than feasible available alternatives;

u. That the Monarc offers no improvement in efficacy compared to non-mesh repairs and non-mesh repairs do not place the obturator or pudendal nerve at risk acutely or over time;

v. That use of the Monarc put the patient at greater risk of requiring additional surgery than feasible available alternatives;

w. That removal of the Monarc due to complications may significantly impair the patient's quality of life;

x. That complete removal of the Monarc may not be possible;

y. That complete removal of the Monarc may not result in complete resolution of the complications, including pain;

z. The foreseeable and unavoidable risk of acute obturator, pudendal, and/or ilioinguinal neuralgia or obturator, pudendal, and/or ilioinguinal neuralgia occurring months or years after implantation;

aa. The magnitude of the risk of obturator and/or pudendal neuralgia; and

bb. The risk of permanent injury and pain to the muscles and soft tissues of the pelvic floor that may occur acutely after implantation or become symptomatic months or years after implantation.

153. AMS Defendants failed to adequately instruct Plaintiff and her healthcare providers regarding property candidates for, as well as the safest and most effective methods of, implantation and use of AMS Defendants' Monarc. AMS Defendants also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Monarc, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Product. AMS Defendants intentionally, recklessly, and maliciously misinterpreted the safety, risks, and benefits of AMS Defendants' Pelvic Mesh Products, including the Monarc at issue in this case, understating the risks and exaggerating the benefits in order to advance its own financial interests, with wanton and willful disregard for Plaintiff's rights and health.

154. Had AMS Defendants properly and adequately warned and instructed Plaintiff and her healthcare providers with regarding to the Monarc's Risks and Potential Complications, upon

information and belief, Plaintiff would not have been recommended implantation of the Monarc, and Plaintiff would not have proceeded with implantation of the Monarc, thus avoiding the injuries Plaintiff has alleged herein.

155. As a proximate result of AMS Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Monarc device at issue in this case, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages. In addition or in the alternative, Plaintiff has suffered an aggravation, exacerbation, and/or acceleration of her pre-existing injuries or conditions.

156. AMS Defendants, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

157. As a direct and proximate result of AMS Defendants' failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Monarc.

158. As a direct and proximate result of the wrongful acts and omissions of AMS Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages.

159. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

160. WHEREFORE, Plaintiff demands judgment against AMS Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

DAMAGES

161. Plaintiff realleges and incorporates by reference 1-160 of this Complaint as if fully set forth herein and further alleges as follows.

A. General and Special Damages

162. The injuries suffered by Plaintiff were caused by the wrongful acts and omissions of AMS Defendants. As a direct and proximate result of having the Monarc implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include, inter alia, any of the following: neuromuscular pain, pelvic pain, extrapelvic pain, groin pain, thigh pain, pelvic floor tension myalgia, complex regional pain syndrome, recurrent urinary tract infections, chronic dyspareunia, bowel and bladder dysfunction, and anorectal pain. Further, Plaintiff has undergone surgical revision of the Monarc device and will likely undergo additional medical treatment and procedures. In addition or in the alternative, Plaintiff has suffered an aggravation, exacerbation, and/or acceleration of her pre-existing injuries or conditions.

163. Plaintiff has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. Plaintiff seeks compensation for her past and future medical expenses, past and future loss of earning capacity, past and future physical impairment, past and future physical disfigurement, past and future physical pain and suffering, and past and future mental anguish and emotional distress.

B. Exemplary Damages

164. At all times relevant herein, AMS Defendants:

a. Knew that their Pelvic Mesh Products, including the Monarc, were dangerous, ineffective, and caused significant, life-altering complications

and side-effects;

b. Concealed the dangers and health risks from Plaintiff, physicians, hospitals, other medical providers, the FDA, its users and the public at large;

c. Made misrepresentations to Plaintiff, physicians, hospitals, other medical providers, its users and the public at large as to the safety and efficacy of their Pelvic Mesh Products, including the Monarc; and

d. With full knowledge of the health risks associated with their Pelvic Mesh Products, including the Monarc, and without adequate warnings of the same, manufactured, designed, marketed, promoted, developed, sold and/or distributed their Pelvic Mesh Products, including the Monarc, for routine use.

165. AMS Defendants, by and through their officers, directors, managing agents, authorized sales representatives, employees and/or other agents engaged in acts and/or omissions involving gross negligence and a subjective awareness of an extreme degree of risk, indicating conscious indifference to the rights, safety, or welfare of others. As such, the conduct of Defendants warrants the imposition of exemplary damages under all applicable legal standards.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands trial by jury, and prays that, after AMS Defendants are served with citation and ordered to appear herein, she be awarded a judgment against AMS Defendants as follows:

1. A judgment against AMS Defendants holding them liable for compensatory damages in a reasonable amount determined to be fair and just by the jury in this cause sufficient to adequately compensate Plaintiff for her harms and losses, including but not limited to damages:

a. For reasonable and necessary medical expenses incurred in the past;

b. For reasonable and necessary medical expenses, which, in all reasonable probability, she will incur in the future;

c. For lost earnings/loss of earning capacity sustained in the past;

d. For lost earnings/loss of earning capacity which, in all reasonable probability, she will sustain in the future;

e. For physical impairment sustained in the past;

f. For physical impairment which, in all reasonable probability, she will sustain in the future;

g. For physical disfigurement sustained in the past;

h. For physical disfigurement which, in all reasonable probability, she will sustain in the future;

i. For physical pain and suffering sustained in the past;

j. For physical pain and suffering which, in all reasonable probability, she will sustain in the future;

k. For mental anguish and emotional distress sustained in the past;

l. For mental anguish and emotional distress which, in all reasonable probability, she will sustain in the future;

2. For punitive and exemplary damages in a reasonable amount determined to be fair and just by the jury;

3. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to which she is entitled; and

4. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues in the above captioned matter.

Date: September 3, 2021

Respectfully submitted,

/s/ Laura J. Baughman
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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of September, 2021, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Laura J. Baughman
Laura J. Baughman